



UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM:

Feb 20, 2019

Subject: Risk Assessment for the New Active Ingredient 1,2 Hexanediol as a Non-food Contact Cleaner

PC Code(s): 141001	DP Barcode: 450653; 441516 (parent)
Decision No.: 528405	Registration Number: 91176-R, 91176-E
Regulatory Action: PRIA RA	CAS No(s): 6920-22-5

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This document provides the human health and ecological risk assessment conducted in support of the PRIA registration of 1,2 hexanediol as a cleaner, deodorizer, and sanitizer for use on hard, non-porous, non-food contact surfaces in commercial, institutional, and residential settings.

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1.0 EXECUTIVE SUMMARY

Skirdel, LLC, D/B/A Protein Express Laboratories has submitted a request for two end-use products (PELS 421 and PELS 422, EPA Reg. No. 91176-R, 91176-E, respectively) containing the proposed new active ingredient, 1,2 Hexanediol. These products are intended to be used as a cleaner, deodorizer, and sanitizer for use on hard, non-porous, non-food contact surfaces in commercial, institutional, and residential settings. The proposed labels (drafted April 11, 2018) are attached in Appendix B.

Human Health Risk Summary

The Agency is bridging the 1,2-hexanediol human health risk assessment to risk assessment previously performed for propylene glycol. No risks of concern were identified for these potential uses of 1,2-hexanediol.

Ecological Risk Summary

1,2 hexanediol is expected to be stable to hydrolysis and aqueous photolysis. Atmospheric oxidation and soil metabolism are expected to be the most significant routes of dissipation, however, based on the use pattern, environmental exposure is anticipated to be minimal based on an air-drying step within the use directions.

The Agency is bridging the 1,2-hexanediol ecological risk assessment to risk assessments previously performed for propylene glycol. Propylene glycol is considered practically non-toxic to birds, freshwater fish and invertebrates, and freshwater aquatic plants. No risks of concern are anticipated for 1,2-hexanediol based on minimal exposure and low toxicity.

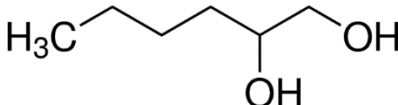
2.0 INTRODUCTION

2.1 Chemical Identity

Table 1 below presents the chemical identification of 1,2 hexanediol.

Table 1: Chemical Identification of 1,2 Hexanediol

Chemical Name	1,2-Hexanediol
Chemical Classification	1,2 diol
PC Code	141001
Smiles Code	OCC(O)CCCC
CAS Number	6920-22-5
Molecular Formula	C ₆ H ₁₄ O ₂
Molecular Weight (grams/mole)	118.17

Molecular Structure	
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2.2 Registered Products

Protein Express Laboratories has submitted labels for two end-use products, PELS 421 and PELS 422 (EPA Reg. No. 91176-R, 91176-E, respectively) which contain 1,2 hexanediol at 3.03% and 4.25%, respectively. There is no manufacturing use product (MUP) for 1,2 hexanediol.

2.3 Use Pattern

Proposed 1,2 hexanediol products are labeled for use in commercial, institutional, and residential settings as a cleaner, disinfectant, and sanitizer for use on hard, non-porous, non-food contact surfaces. Use sites include floors/walls of kitchens and restaurants, kennels, toilets, non-food contact surfaces of poultry farms, hospitals, and non-critical, hard, non-porous medical device surfaces, etc. Likewise, they are labeled to be used to deodorize, inhibit the growth of algae/slime-forming bacteria on hard, non-porous surfaces, and remove mold, mildew, and stains.

The directions for use indicate that application of the product should thoroughly wet the surface and the surface should be allowed to air dry.

3.0 HUMAN HEALTH RISK ASSESSMENT

The Agency has concluded that 1,2-hexanediol is structurally similar to propylene glycol. This is based on the structure and physical-chemical properties of both compounds. Therefore, the Agency will cite the propylene glycol Reregistration Eligibility Decision (RED; EPA-739-R-06-002), the Preliminary Work Plan (PWP; EPA-HQ-OPP-2013-0218) and the Final Work Plan (FWP; EPA-HQ-OPP-2013-0219) regarding the 1,2-hexanediol human health risk assessment.

There is no evidence of adverse effects at doses of propylene glycol up to the established limit dose in repeat-exposure dermal and inhalation toxicity studies. Therefore, the Agency has not established toxicity endpoints for propylene glycol. The Agency is not establishing toxicology endpoints for 1,2-hexanediol based on the similarity to propylene glycol and the lack of toxic effects seen in submitted studies.

In the RED the Agency concluded that propylene glycol poses no toxicological concerns due to its low toxicity; therefore, no toxicological endpoints of concern were developed. Based on a review of the available toxicity data for propylene glycol, the Agency concludes that for this new active ingredient registration of 1,2-hexanediol, this chemical does not pose a toxicological concern when used according to the potential uses. No additional toxicity data requirements are anticipated at this time for registration of this new active ingredient. This conclusion is based on the results of toxicity testing of propylene glycol at dose levels near or above testing limits. No

significant toxicity was observed in any of the animal toxicity studies in the existing toxicological database.

A review of the 1,2-hexanediol acute dermal, oral and inhalation toxicity data showed that the chemical did not induce deaths at the highest concentrations tested. Therefore, there is no risk from acute exposures to products that harbor 1,2-hexanediol.

3.1 Hazard Characterization

Based on the toxicological database on propylene glycol, 1,2-hexanediol is not expected to be hazardous to human health from exposure when used as an antimicrobial pesticide. There are no toxicological endpoints of concern.

3.2 Dietary Exposure

All labels indicate use on non-food contact surfaces. Therefore, no dietary assessment is needed.

3.3 Drinking Water Exposure

No drinking water risk assessment is needed based on the lack of environmental exposure and toxicity.

3.4 Residential Exposure and Risks

No residential risk assessment is needed based on the lack of toxicity. No endpoints were selected for assessing the dermal, inhalation or incidental oral exposures that are normally included in a residential risk assessment.

3.5 Aggregate Exposure and Risks

No aggregate risk assessment is needed based on the lack of toxicity. No endpoints were selected for assessing the residential dermal, inhalation, or incidental oral exposures and the dietary food and water exposures that are normally included in an aggregate risk assessment.

3.6 Occupational Exposures and Risks

No occupational risk assessment is needed based on the lack of toxicity. No endpoints were selected for assessing the dermal or inhalation exposures that are normally included in an occupational risk assessment.

3.7 Cumulative Exposure

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to 1,2 hexanediol and any other substances and 1,2 hexanediol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that 1,2 hexanediol has a common mechanism of toxicity with other substances. In 2016, EPA's Office of Pesticide Programs (OPP) released a guidance document entitled, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis*

[<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework>]. This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs)¹ and conducting cumulative risk assessments (CRA)². During Registration Review, the Agency will utilize this framework to determine if the available toxicological data for 1,2 hexanediol suggests a candidate CMG may be established with other pesticides. If a CMG is established, a screening-level toxicology and exposure analysis may be conducted to provide an initial screen for multiple pesticide exposure.

4.0 ENVIRONMENTAL RISK ASSESSMENT

4.1 Environmental Fate

The registrant proposed that based on structural similarities, environmental fate data for 1,2 octanediol, 1,2 butanediol, and 1,2 propanediol (propylene glycol) could be bridged for 1,2 hexanediol. The Agency agrees that based on their similar chemical structures (1,2 diols), all are expected to share similar environmental fate characteristics.

1,2 hexanediol does not contain any hydrolysable functional groups and does not absorb light at wavelengths above 200 nm and is therefore, expected to be stable to both hydrolysis and aquatic photolysis.

No down-the-drain exposure is expected due to the air dry requirement on the product label, therefore, WWTP data have been waived. However, based on estimates of potential sorption and degradation, it is estimated that 98% of 1,2 hexanediol entering a waste water treatment plant (WWTP) would be released (EPI Suite V 4.1). If the uses were to be changed/updated where down-the-drain exposure would be expected, WWTP data would then be anticipated to be required.

Propylene glycol has a half-life of 4 days in aerobic soils and 9 days in anaerobic soils (US EPA, 2007). It is expected that 1,2 hexanediol will have slightly higher half-lives due to the slightly longer carbon chain (6-carbon chain instead of 3-carbon chain). The half-lives are expected to be comparable.

The air half-life of propylene glycol is relatively short, estimated to be about 32 hours, due to the induced photochemical reaction with hydroxy-radical in the atmosphere (US EPA, 2007).

¹ *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999)

² *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity* (USEPA, 2002)

Likewise, 1,2 hexanediol is expected to share a similar half-life as propylene glycol based on the similar chemical structure.

Table 2 below lists the environmental fate and physical properties of 1,2 hexanediol.

Table 2: Fate and Physical Properties of 1,2 Hexanediol

Guideline No.	Guideline Name/Property	Value	Source/Comment
835.2120	Hydrolysis	Stable	Based on structure
835.2240	Aqueous Photolysis	Stable	MRID 50566401
835.4100	Aerobic Soil Metabolism	~4 days	Bridging with propylene glycol
835.4200	Anaerobic Soil Metabolism	~9 days	Bridging with propylene glycol
850.6800, 835.3110, 835.3220, 835.3280, and 835.3240	WWTP Data	Waived	No Exposure
830.7950	Vapor Pressure (at 25°C)	0.02 mm Hg	EPI Suite V 4.11
830.7370	Dissociation Constant (pKa)	NA	Does not dissociate in water
830.7550	Log Kow	0.69	EPI Suite V 4.11
NA	Henry Law Constant (atm·m ³ /mol)	4.06x10 ⁻⁷	EPI Suite V 4.11

4.2 Ecological Exposure

No ecological exposure is expected from the use of 1,2 hexanediol products as a cleaner/sanitizer because all product labels indicate that the surface should be allowed to air dry.

4.3 Ecological Effects

Since no ecological exposure is expected for the proposed uses of 1,2 hexanediol, only a minimal ecotoxicity database is needed for labeling purposes. For this purpose, the Agency believes that ecotoxicity database for 1,2 propanediol (propylene glycol) is sufficient to supplement data for 1,2 hexanediol. This is because both are 1,2, diols connected to similar-sized, short carbon chains and therefore it can be reasonably assumed they will react similarly to non-target organisms.

Therefore, the Agency has cited the propylene glycol ecotoxicity endpoints presented in the Reregistration Eligibility Decision (RED) and the Registration Review Preliminary Work Plan (PWP) and Final Work Plan (FWP). These documents are available at www.regulations.gov in docket numbers EPA-HQ-OPP-2006-0831 (RED) and EPA-HQ-OPP-2013-0218 (Registration Review), respectively.

Based on data reviewed in support of the REDs, propylene glycol inactivates target pests by denaturing proteins found in cell membranes and viral protein coats. This leads to the target pests losing structural integrity and losing the ability to cause infections. For non-target aquatic animals, these chemicals act acutely by narcosis, a non-specific mechanism of action.

Propylene glycol shows very low acute toxicity to terrestrial and aquatic animals. The toxicity endpoints (presented below in table 3) are based on the results of toxicity studies submitted by registrants to meet the Agency's ecological effects data requirements for the uses of propylene glycol. Additional information was located in the EPA Office of Research and Development's (ORD's) ECOTOX database, which provides summary endpoints from the open scientific literature as well as studies submitted to the Agency. For missing data, the structure activity program ECOSAR v1.10 was used to estimate endpoint values.

Propylene glycol is considered practically non-toxic to birds, freshwater fish and invertebrates, and freshwater aquatic plants.

Table 3: Selected Ecotoxicity Endpoints for Propylene Glycol

Receptor Group	Surrogate Species	Risk Scenario	Toxicity Endpoint ^a	Reference (MRID)
Birds	Northern bobwhite quail	Acute oral	LD ₅₀ > 2,000 mg/kg-bw	43762301
Mammals	Rat	Acute	LD ₅₀ 8,000-46,000 mg/kg-bw	See Appendix A of PWP
Freshwater fish	Fathead minnow	Acute	96-hr LC ₅₀ = 710 ppm	Pillard, 1995 (ECOTOX reference #13727)
Freshwater invertebrates	Waterflea	Acute	48-hr EC ₅₀ > 110 ppm ^a	43762302
Estuarine/marine fish	Generic fish	Acute	96-hr LC ₅₀ > 24,000 ppm ^a	ECOSAR v1.10
Estuarine/marine invertebrates	Mysid	Acute	24-Hr Static LC ₅₀ > 10,000ppm ^a	Price <i>et al.</i> , 1974 (ECOTOX reference #2408)
			96-hr LC ₅₀ > 100,000 ppm ^a	ECOSAR v1.10
Aquatic Plants	Green algae	Nonlisted species	96-hr IC ₅₀ > 5,000 ppm ^a	ECOSAR v1.10
		Listed Species	96-hr Chv > 300 ppm ^a	

a- For additional studies, definitive values, and ECOSAR Version 1.10 results, see the propylene glycol Registration Review Preliminary Work Plan (PWP) Appendix C available at www.regulations.gov in docket number (EPA-HQ-OPP-2013-0218). Non-definitive values are provided in this table to show that propylene glycol has low toxicity and is considered potentially non-toxic. The green algae data and acute animal data were required only for hazard labeling purposes. No risk assessment is anticipated.

There are no submitted chronic data in the files and no comparable endpoints found in the open literature ECOTOX database. Estimates of propylene glycol (neutral organics class) chronic toxicity to aquatic animals using ECOSAR v1.10 range from 413 to 1,422 mg/L for freshwater animals and 484 to 26,526 mg/L for saltwater animals (Table 4).

Table 4: Chronic Toxicity of Propylene Glycol to Aquatic Animals

Species	Propylene Glycol <i>Chv</i>	Reference
Fish, Freshwater	1,422 mg/L	ECOSAR v1.10
Daphnid, Freshwater Invertebrate	413 mg/L	ECOSAR v1.10
Fish, Saltwater	484 mg/L	ECOSAR v1.10
Mysid, Estuarine/Marine Invertebrate	23,526 mg/L	ECOSAR v1.10

Chv = geometric mean of a NOEC and LOEC value

4.4 Ecological Risk Characterization

Due to lack of ecological exposure, 1,2 hexanediol is not expected to pose an ecological risk to non-target terrestrial or aquatic organisms.

For labeling purposes, 1,2 hexanediol is considered practically non-toxic to birds, freshwater fish and invertebrates, and freshwater aquatic plants.

5.0 REFERENCES

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- U.S. Environmental Protection Agency (EPA). 2013c. Propylene Glycol, Dipropylene Glycol, and Triethylene Glycol Final Work Plan (FWP). Registration Review: Initial Docket. Case Numbers: 3126 & 3046. Available at www.regulations.gov Docket Numbers: EPA-HQ-OPP-2013-0218 & EPA-HQ-OPP-2013-0219. Dated Dec 2013.
- U.S. Environmental Protection Agency (EPA). 2017a. Propylene Glycol, Dipropylene Glycol, and Triethylene Glycol Proposed Interim Registration Review Decision. Case

Numbers: 3126 & 3046. Available at www.regulations.gov Docket Numbers: EPA-HQ-OPP-2013-0218 & EPA-HQ-OPP-2013-0219. Dated March 2017.

U.S. Environmental Protection Agency (EPA). 2017b. Propylene Glycol, Dipropylene Glycol, and Triethylene Glycol Interim Registration Review Decision. Case Numbers: 3126 & 3046. Available at www.regulations.gov Docket Numbers: EPA-HQ-OPP-2013-0218 & EPA-HQ-OPP-2013-0219. Dated Dec 2017.

Appendix A: Human Health Toxicity Profile

Acute Toxicity Profile

Guideline	Study Type	MRID No./Citation	Results	Toxicity Category
870.1100	Acute Oral – Rat	46892501 46892509 Clark, 1979 Bartsch, 1976 Sax, 1979 Layton, 1987	LD ₅₀ = 8000-46000 mg/kg	IV
870.1300	Acute Inhalation – Rat	Konradova, 1978	LC ₅₀ > 2.0 mg/L (no deaths)	IV
870.2400	Acute Eye Irritation – Rabbit	46892104 46892502 46892508 Clark, 1979 Draize, 1954 Guillot, 1982	Non-irritant	IV
870.2500	Acute Skin Irritation – Rabbit	Clark, 1979	Non-irritant	IV
870.2600	Skin Sensitization – Guinea pig	Kero, 1980	Non-sensitizer	N/A

Propylene glycol and as expected, 1,2-hexanediol, have low acute toxicities (Category IV) with high LD₅₀ ranging from 8000-46,000 mg/kg for rodents and 18,000-20,000 mg/kg for both rabbits and guinea pigs. Signs of nervous system toxicity were reported in the rabbit and guinea pig at lethal doses whereas effects of this nature were only evident in one study with mice at LD₅₀ values of 23,000-24,900 mg/kg (MRID 46892501; 46892509; Clark, 1979; Bartsch, 1976; Sax, 1979; Layton, 1987).

In an acute inhalation toxicity study (Konradova, 1978), propylene glycol induced degeneration of goblet cells (+69%) in the tracheal lining of rabbits after 20 and 120 minutes of aerosol exposure; no other toxicological effects were observed. Propylene glycol has been classified as Category IV for acute inhalation.

Propylene glycol has been classified as Category IV for eye irritation. There were no treatment-related effects on the corneas of rabbits instilled with propylene glycol from 0.1-0.5 mL (MRID 46892104; 46892502; 46892507; Clark, 1979; Draize, 1944; Guillot, 1982).

Acute dermal toxicity studies are not available for propylene glycol, however, propylene glycol has been classified as not a skin sensitizer (MRID 46892104).

Subchronic Toxicity Profile

Propylene glycol exhibits low toxicity to animals. No adverse toxicological effects were observed in rats exposed to 2500 mg/kg/day via diet (MRID 46892504). In another study, rats exposed to propylene glycol via drinking water for 140 days exhibited clinical signs (CNS depression and minor liver toxicity) at 13,200 mg/kg/day, a dose level above the testing limit dose (Seindenfeld, 1932).

Rats exposed to propylene glycol (1.0 or 2.2 mg/L) vapors for 90 days, 6 hours/day, 5 days/week, experienced decreases in body weight and food consumption, although changes in respiratory rates, minute volumes, or tidal volumes during exposure. A significant increase in the number of goblet cells in the nasal passages of the mid- and high-dose animals was observed from exposure to propylene glycol (MRID 46892103).

Developmental and Reproductive Toxicology

Open literature developmental and reproductive toxicity studies on propylene glycol showed minimal evidence of toxicity at relatively high concentrations that exceed the established limit dose of 1000 mg/kg/day.

Chronic Toxicity and Carcinogenicity

Open literature studies have shown that propylene glycol is not carcinogenic in rodent and non-rodent species. In addition, mammalian chronic toxicity studies have shown that systemic adverse effects were noted at doses of propylene glycol that exceed the limit dose of 1000 mg/kg/day.

In a continuous-exposure inhalation study, rats were exposed to 0.17-0.35 mg/L propylene glycol for 18 months and a LOAEL of 0.35 mg/L was established based on a 50% increase in body weight (Robertson, 1947).

Mutagenicity

Open literature studies on propylene glycol have shown that the chemical does not induce mutagenicity or genotoxicity.

Neurotoxicity

Toxicity studies on propylene glycol have shown loss of balance, marked depression, and analgesia in mice, rabbits, and guinea pigs after a single exposure of 18,400-24,900 mg/kg/day (Braun, 1936; Laug, 1939; Smyth, 1941; Latven, 1939). Central nervous system depression was

also observed in rats exposed to propylene glycol at doses above 13,200 mg/kg/day in drinking water for 140 days (Seidenfeld, 1932).

Metabolism and Excretion

A maximum concentration of 29.21 ± 2.92 mM propylene glycol was found in the blood of rats after 2 h of exposure at 77.28 mmol/kg (Morshed, 1988). Propylene glycol was readily absorbed in the GI tract of several animals in other studies and the absorption was rapid and complete and broken down into glycogen (Hanzlik, 1939; Opitz, 1958; Salter, 1935; Van Winkle, 1941).

Within 10 hours of oral administration of propylene glycol to humans, 20-25% of the 70 g was excreted via the urine and 20% of a 150 g dose given to dogs was excreted within 24 h (Hanzlik, 1939).

Dermal Absorption

At the time of the publishing of the FWP for propylene glycol, there were studies available for propylene glycol and skin absorption. However, propylene glycol has been found to penetrate the outermost layer of the epidermis, thus it is used as a cosmetic ingredient in many products. However, there is a lack of irritation from acute dermal studies and there's no evidence of systemic adverse effects from chronic dermal studies (MRID 46892301; Clark, 1979).

Immunotoxicity

According to the FWP published in 2013, an immunotoxicity study is not required based on a weight of evidence approach for propylene glycol.

Appendix B: Proposed Labels

[Master Label for PELS 421. Reg No. 91176-R]

[Brackets throughout label indicate optional or instructional language]

PELS 421

One-step liquid cleaner, deodorizer, and sanitizer for use on hard, non-porous, non-food contact surfaces.

For Commercial, Non-medical Institutional, and Residential Use

Active Ingredient:

1,2-Hexanediol.....3.03%

Other Ingredients.....96.97%

Total.....100.00%

KEEP OUT OF REACH OF CHILDREN

EPA Reg. No: 91176-TBD **EPA Est. No.:** XXXXX-XX-XXX **Net Contents:**
Manufactured By:

Skirdle, LLC DBA Protein Express Laboratories 600 Vine St, Suite 2800
 Cincinnati, Ohio 45202

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

TO CLEAN AND DEODORIZE HARD, NON-POROUS SURFACES

Use this product to clean and remove stains and to control odor and stain causing bacteria or other pests on [surfaces listed in Use Sites below]. Apply solution to hard, non-porous, non-food contact surfaces, thoroughly wetting surface with a cloth, mop, sponge, or sprayer, or by immersion. Allow to air dry.

SANITIZER

Use this product to sanitize [surfaces listed in Use Sites below] in one step. Apply solution to hard, non-porous, non-food contact surfaces, thoroughly wetting surface with a cloth, mop, sponge, or sprayer, or by immersion. Reapply as necessary to ensure that surface remains wet for required contact time. Allow to air dry.

Organisms	ATCC	Contact Time
<i>Enterobacter aerogenes</i>	13048	5 minutes
<i>Staphylococcus aureus</i>	6538	5 minutes
<i>Staphylococcus aureus MRSA</i>	33592	5 minutes

Use Sites (hard, non-porous, nonfood contact surfaces only)

- Airplanes

- Airports
- Ambulances
- Animal laboratories
- Athletic facilities
- Barber shops
- Bars - nonfood contact surfaces only
- Bathroom fixtures
- Bathtubs
- Boats
- Buses
- Business and office buildings
- Cabinets
- Cages
- Camp grounds
- Campers
- Cars
- Chairs
- Chicken farms – nonfood contact surfaces only
- Clinics
- Coils and drain pans of air conditioning and refrigeration equipment and heat pumps
- Colleges
- Conductive flooring
- Convenience stores
- Correctional facilities
- Dairy farms – nonfood contact surfaces only
- Day care centers
- Dental offices
- Desks
- Doorknobs
- Dressing rooms
- Emergency (Police) (EMS) (Fire) (Rescue) vehicles
- Exercise facilities
- Factories
- Farms
- Floors
- Garbage cans
- Hog farms - nonfood contact surfaces only
- Hotels

- Institutional facilities
- Institutional kitchen floors/walls
- Institutions
- Kennel runs
- Kennels
- Kitchens floors/walls
- Locker rooms
- Mobile homes
- Motels
- Nurseries
- Nursing homes
- Pet animal quarters
- Pet shops
- Playground equipment
- Poultry farms – nonfood contact surfaces only
- Prisons
- Public facilities
- Public rest rooms
- Refrigerated storage and display equipment
- Restaurants (floors/walls)
- Salons [Beauty] [Tanning]
- Schools
- Ships
- Shower and bath areas
- Shower stalls [Fiberglass]
- Showers
- Sick Rooms
- Sinks [bathroom] [Fiberglass]
- Tanning beds
- Taxis
- Telephones
- Tiles, glazed
- Toilet bowl surfaces
- Toilet bowls – exterior surfaces only
- Toilets – exterior surfaces only
- Trailers
- Trains
- Transportation terminals

- Tubs [Fiberglass]
- Turkey farms – nonfood contact surfaces only
- Ultrasonic baths
- Universities
- Urinals – exterior surfaces only
- USDA inspected food processing facilities – nonfood contact surfaces only
- Walls
- Whirlpool bathtubs
- Zoos

Optional Label Claims:

- Deodorizes
- Eliminates Odors
- Inhibits the growth of algae/ slime-forming bacteria and mildew on hard, non-porous surfaces.
- Removes mold and mildew which cause staining, odor, discoloration, and deterioration.
- Removes stains.

STORAGE AND DISPOSAL

Do not contaminate food or feed by storage or disposal

STORAGE: Store away from children. Reclose cap tightly after use. Store this product upright in a cool dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood areas with large quantities of water.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

OR

To avoid waste, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Skirdle, LLC DBA Protein Express Laboratories
PELS 421 (91176-R)

A420 – New Active Ingredient – March 17, 2017, Label Version (2) April 11, 2018

[Master Label for PELS 422. Reg No. 91176-E]

[Brackets throughout label indicate optional or instructional language]

PELS 422

One-step liquid cleaner, deodorizer, sanitizer, and disinfectant for use on hard, non-porous, non-food contact surfaces.

For Hospital, Commercial, Institutional, and Residential Use

Active Ingredient:

1,2-Hexanediol.....4.25%

Other Ingredients.....95.75%

Total.....100.00%

KEEP OUT OF REACH OF CHILDREN

EPA Reg. No: 91176-TBD

EPA Est. No.: XXXXX-XX-XXX

Net Contents:

Manufactured By:

Skirdle, LLC DBA Protein Express Laboratories
600 Vine Street, Suite 2800
Cincinnati, Ohio 45202

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

TO CLEAN AND DEODORIZE HARD, NON-POROUS SURFACES

Use this product to clean and deodorize [surfaces listed in Use Sites below]. Apply solution to hard, non-porous surfaces, thoroughly wetting surface with a cloth, mop, sponge, or sprayer, or by immersion. Allow to air dry.

DISINFECTANT

Use this product to disinfect [surfaces listed in Use Sites below] in one step. Apply solution to hard, non-porous surfaces by spraying 6-8 inches from the surface. Reapply as necessary to ensure that surface remains wet for required contact time. Allow to air dry.

Organisms	ATCC	Contact Time
<i>Pseudomonas aeruginosa</i>	15442	10 minutes
<i>Salmonella enterica</i>	10708	10 minutes
<i>Staphylococcus aureus</i>	6538	10 minutes
Influenza A H1N1	VR-1520	10 minutes

SANITIZER

Use this product to sanitize [surfaces listed in Use Sites below] in one step. Apply solution to hard, non-porous, non-food contact surfaces, thoroughly wetting surface with a cloth, mop, sponge, or sprayer, or by immersion. Reapply as necessary to ensure that surface remains wet for required contact time. Allow to air dry.

Organisms	ATCC	Contact Time
<i>Enterobacter aerogenes</i>	13048	5 minutes
<i>Staphylococcus aureus</i>	6538	5 minutes
<i>Staphylococcus aureus MRSA</i>	33592	5 minutes
<i>Streptococcus pyogenes</i>	19615	5 minutes
<i>Escherichia coli O157:H7 (E. coli)</i>	35150	5 minutes

Use Sites (hard, non-porous, nonfood contact surfaces only)

- Airplanes
- Airports
- Ambulances
- Animal laboratories
- Athletic facilities
- Barber shops
- Bars – nonfood contact surfaces only
- Bathroom fixtures
- Bathtubs
- Boats
- Buses
- Business and office buildings
- Cabinets
- Cages
- Camp grounds
- Campers
- Cars
- Chairs
- Chicken farms – nonfood contact surfaces only
- Clinics
- Coils and drain pans of air conditioning and refrigeration equipment and heat pumps
- Colleges
- Conductive flooring
- Convenience stores
- Correctional facilities
- Dairy farms – nonfood contact surfaces only

- Day care centers
- Dental offices
- Desks
- Doorknobs
- Dressing rooms
- Emergency (Police) (EMS) (Fire) (Rescue) vehicles
- Exercise facilities
- Factories
- Farms
- Floors
- Garbage cans
- Health Care Facilities
- Hog farms - nonfood contact surfaces only
- Hospitals
- Hotels
- Institutional facilities
- Institutional kitchen floors/walls
- Institutions
- Kennel runs
- Kennels
- Kitchens floors/walls
- Locker rooms
- Medical Offices
- Medical Related facilities
- Mobile homes
- Motels
- Nurseries
- Nursing homes
- Pet animal quarters
- Pet shops
- Playground equipment
- Poultry farms – nonfood contact surfaces only
- Prisons
- Public facilities
- Public rest rooms
- Refrigerated storage and display equipment
- Restaurants (floors/walls)
- Salons [Beauty] [Tanning]

- Schools
- Ships
- Shower and bath areas
- Shower stalls [Fiberglass]
- Showers
- Sick Rooms
- Sinks [bathroom] [Fiberglass]
- Tanning beds
- Taxis
- Telephones
- Tiles, glazed
- Toilet bowl exterior surfaces
- Toilet bowls – exterior surfaces
- Toilets – exterior surfaces
- Trailers
- Trains
- Transportation terminals
- Tubs [Fiberglass]
- Turkey farms – nonfood contact surfaces only
- Ultrasonic baths
- Universities
- Urinals – exterior surfaces
- USDA inspected food processing facilities – nonfood contact surfaces only
- Walls
- Whirlpool bathtubs
- Zoos

Non-critical, hard, non-porous medical device surfaces*:

- Medical and Hospital Lamps
- Medical and Hospital Scales
- Medical and Hospital Examining tables
- Bed frames
- Bed rails
- Medical and Hospital Beds
- Crutches
- Defibrillators
- Gurneys
- Non-critical hospital and medical equipment
- Rescue tools

- Resuscitators
- Stands
- Stethoscopes
- Stretchers
- Walkers
- Wheel chairs

* This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection

Optional Label Claims:

- Antibacterial
- Deodorizes
- Eliminates Odors
- Sanitizer
- Disinfectant

STORAGE AND DISPOSAL

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